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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,580	09/30/2003	Hassan Serhan	3518.1010-000 (DEP5077)	9958
21125 7590 05/01/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER SWIGER III, JAMES L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,580

Applicant(s)

SERHAN ET AL.

Examiner

James L. Swiger

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-13, 15, 24, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-13, 15, 24, and 37-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6, 11-13, 15, 24, 39 and 40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 11-13, 15, 24, and 37-38, drawn to a fusion device with a solid vertebral structure, classified in class 606, subclass 61.
- II. Claims 39-40, drawn to a intervertebral device with an inflatable balloon, classified in class 606, subclass 192.

Newly submitted claims 39-40 are directed to an invention that is independent or distinct from *the invention originally claimed* for the following reasons.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination of the device with balloon has separate utility such as use in functioning as a prosthesis that does not have an immediate solid structure, or cage, and may also be used to deliver bone cement to another void within the body. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 15, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Zdeblick et al. (US 6,375,655). Zdeblick et al. disclose a fusion device for use in the spine comprising a body (50) having a proximal portion (end @ 52), and a distal portion (opposite proximal end) that defines conduit, defined as an artificial channel or passage (see Fig. 9) that is substantially parallel to the major axis. Zdeblick et al. also disclose a supporting means (see Fig. 2) capable of supporting the vertebrae in a distracted position while the vertebrae fuse (see Fig. 13 c), and wherein the open inside of the

Art Unit: 3733

supporting means is considered a conduit in fluid communication with the conduit of the body or at least the portion as disclosed by Zdeblick et al. (US Patent 6,375,655).

The supporting means also has a height distinct from the width along a cross-section of the body supporting means (see profile in Fig. 2). Also the body or supporting means is capable of distracting vertebrae in that when the body (50) is connected to the supporting means (Fig. 2), it is capable of being turned (Fig. 6) into a position that could expand the vertebrae and distract them (Col. 4, lines 34-45). Further the supporting means may be a cage (Fig. 2) considering its open, hollow surround. The supporting means also maintains a substantial natural angle (see Fig. 3, lines A merging at the narrow end of the supporting means).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. '655 in view of Mathews (US Pub 2003/0028251). Zdeblick et al. disclose the claimed invention except for a supporting means that is a balloon that and materials, used in the supporting implant or in the balloon may facilitate bone growth, or a flowable material. Mathews discloses a spinal device that is capable of being a

Art Unit: 3733

support device as a balloon (see 34, and see pars 0043 to 0045) that is capable of providing support and that may be made of bioactive, or bioresorbable material (par. 0053) and that is flowable (see Pars. 50 and 51, and see Fig. 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zdeblick et al. having at least a balloon and bioactive/resorbably materials in view of Mathews to better support the spine in use.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. '655 in view Nicholson et al. (US Patent 6,258,094). Zdeblick et al. disclose the claimed invention except for specifically a support that is biodegradable. Nicholson et al. discloses a lumbar or vertebrae implant (see Figs. 3-5) having a biodegradable material so the implant better interfaces with the spine as it supports the vertebrae (see Col. 12, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Zdeblick et al. having at least a biodegradable material in view of Nicholson et al. to better have the implant mesh and be incorporate into the spine.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 11-13, 15, 24, and 37-40 have been considered but are moot in view of the new ground(s) of rejection.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

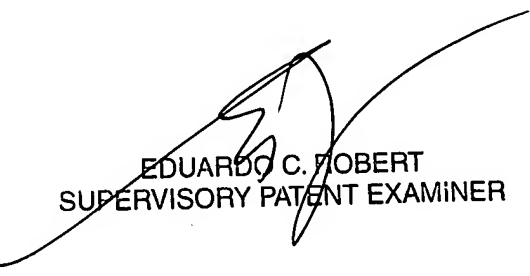
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 4/20/07

JLS


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER